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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,320	11/08/2001	Roman M. Barabolak	112703-211	2531

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BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER

KRASS, FREDERICK F

ART UNIT PAPER NUMBER

1614

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/035,320	Applicant(s) BARABOLAK ET AL.	
	Examiner Frederick F. Krass	Art Unit 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1,3-8,10-18 and 20-24.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached discussion.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

Frederick Krass
Primary Examiner
Art Unit 1614

[Signature]

ATTACHMENT TO ADVISORY ACTION DATED 6/5/05

DISCUSSION

Pending entry of the amendment dated June 15, 2005, the rejections will be as follows:

1) New matter rejection of Claims 1-24:

This rejection is maintained.

Applicant argues that "there is basis for one having ordinary skill in the art to distinguish between surfactants and emulsifiers according to the present claims." (Remarks, p. 5, ¶ 3). Applicant goes onto explain that, "although surface active agents and emulsifiers share similar qualities, a distinction according to the present claims is that some surface active agents have better properties as surfactants than as emulsifiers and some emulsifiers have better properties as emulsifiers than as surfactants as defined above", for example cetylpyridinium chloride. (Remarks, p. 5, ¶ 4, emphasis added).

The examiner can find no specific disclosure in the instant specification to support these allegations. No such distinctions were made there. Moreover, examiner has presented factual, extrinsic evidence to the contrary.

2) Obviousness rejection of claims 1-5, 15, 19-21 and 23 as unpatentable over WO 95/17159:

This rejection is maintained.

Applicant argues that the prior art fails to disclose or suggest an emulsifier "as used according to the instant claims." (Remarks, p. 6, ¶ 4.) Applicant further contends that the Patent Office's assertion that cetylpyridinium chloride is an emulsifier fails to meet the limitation of the present claims that an emulsifier other than CPC be present.

Art Unit: 1614

The examiner does not agree. A mixture of CPC and dodecyl trimethyl ammonium bromide, fairly suggested for the reasons set forth at page 3 of the previous Office Action, would meet the instant limitations since each species has both emulsifying and surfactant qualities at the same time. (This was previously explained at p. 3 of the previous Office action; note also that this position is consistent with Applicant's allegations of the remarks of p. 5, ¶ 4, supra.)

3) Obviousness rejection of claims 1, 6-8, 12-18 and 22 as unpatentable over Hill (USP 5,380,530):

This rejection is maintained.

The reasoning for this ground of rejection was fully set forth at pages 4 and 5 of the previous Office Action. Note that polymethylsiloxanes are not excluded from the instant claims (also discussed in the previous Office action). And, contrary to Applicants arguments (remarks, p. 7, ¶ 1), the fact that compounds are "chemically distinct" does not preclude their combination where they are merely being combined with the expectation of obtaining the expected function of each; this reasoning can apply even when components are from different references. See for example In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). If chemically distinct components can be selected from different references, then they can surely be selected from lists within the same reference, as is the case here.

Moreover, the examiner sees no basis for Applicant's assertion that Hill "is entirely directed to the using the surfactant/polydimethylsiloxane mixture in a gum coating, which teaches away from the use of the claimed emulsion in the water soluble portion of the chewing gum". (Remarks, p. 7, ¶ 1). Hill in fact appears to disclose exactly that, and the section referenced by Applicant (col. 13, lines 49-52 of the prior art) does not state that the coating is water-insoluble; rather, it states that the surfactant and/or emulsifier is incompatible with the polydimethylsiloxane, not with water. Moreover, the water-soluble portion of Applicant's gum is also in the coating; see claim 14.

Art Unit: 1614

4) Obviousness rejection of claim 24 as unpatentable over WO 95/17159 in view of Gaffar (USP 5,472,685):

This rejection is maintained for the reasons already of record.

5) Obviousness rejection of claims 6 and 9-11 as unpatentable over Hill (USP 5,380,530) in view of WO 95/17159:

This rejection is maintained, for substantially the same reasons discussed in subsection "3)" supra.

6) Obviousness-type double patenting rejection of claims 1-22 as being unpatentable over claims 108 of USP 6,436,369, taken in view of Hill (USP 5,380,530):

This rejection is maintained, pending submission of a terminal disclaimer.

ALLOWABLE SUBJECT MATTER

The examiner has carefully considered all of Applicant's arguments, and in doing so believes that claim 6 (and those claims specifically depending therefrom) would be allowable if rewritten as follows:

Claim 6. An anti-plaque chewing gum comprising:
a water insoluble portion; and
a water soluble portion including an aqueous emulsion comprising a mixture of water, an emulsifier, triclosan, and cetylpyridinium chloride.

Recitation of an aqueous emulsion would provide a clear line of distinction over the prior art, which is explicitly limited to melt-emulsions, i.e. emulsions not containing water. See col. 20, lines 30-38; see also example 2 at col. 22, which describes a "solid, flaked emulsion." The prior art never suggests adding water, which is consistent with teachings of an oil, not water-based, emulsion: see for example col. 11, lines 45 and 46, and working example 1 at col. 22.

Moreover, Applicant has persuasively and factually demonstrated that inclusion of triclosan and CPC, in the form of an aqueous emulsion in the water-soluble part of a chewing gum comprising a water-

Art Unit: 1614

soluble and water-insoluble portion, provides unexpected efficacy (thus allowing lower amounts of active agent to be used) with a decrease in negative sensory effects over the corresponding gum comprising triclosan or CPC individually: see the first paragraph of p. 2 of the instant specification, and the comparative data presented at the table at p. 13. These improved results could in no way have been predicted from the prior art of record.

And finally, recitation of an emulsifier in the context an aqueous mixture present in the water-soluble portion of a gum, would overcome the new matter rejection since in that particular context it is readily apparent that the emulsifier is maintaining the emulsion of triclosan, CPC and water in combination, apart from the other components of the water-soluble portion of the chewing gum.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/035,320

Page 6

Art Unit: 1614

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read "Fred Krass", written in a cursive style.